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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/932,227	09/17/1997	ERIC T. FOSSEL		5092

7590 09/26/2003

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EXAMINER
MULLIS, JEFFREY C

ART UNIT	PAPER NUMBER
1711	

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/932,227	FOSSEL, ERIC T.	
	Examin r	Art Unit	
	Jeffrey C. Mullis	1711	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-35,38-44,47-53,56-59 and 61-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42-44,47-50 and 74* is/are allowed.

6)☒ Claim(s) *33-35,38-41,51-53,56-59,61-73 and 75-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's amendment to the specification is in non-grammatical English and is furthermore confusing since applicant has apparently taken only portions of claims and inserted them into the specification. While it is not the position of the Examiner that it would be proper to insert entire claims into the specification in that inserting entire claims into the specification would require that the specification refer to claims, nonetheless applicant's amendment is confusing given that only portions of the claims have been inserted and therefore many sentences are incomplete and missing subjects and verbs etc. Note in this regard for instance "(F)urther comprising a sufficient amount of ionic salt such as to create an ionic environment to cause absorption of the nitric oxide precursor" or "(F)urther comprising a sufficient amount of ionic salt slat (sic) such as to create an ionic strength environment within the liposome to cause tissue absorption of the nitric oxide precursor" etc. Furthermore insertion of the subject matter into the claims of the specification without reciting how such subject matter is pertinent is confusing. Apparently the subject matter inserted on page 6 are various embodiments, yet page 6 does not recite that the subject matter inserted is considered various embodiments of applicant's invention.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The

substitute specification filed must be accompanied by a statement that it contains no new matter.

The amendment filed 3-20-03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification as filed does not disclose the use of "effective dose of a precursor to the endothelial relaxing factor, nitric oxide".

Applicant is required to cancel the new matter in the response to this Office action.

Claims 33-35, 38-41,64-69,70- 73, 75-77 and 79-81 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not broadly disclose a "method of topically treating a medical condition" or conditions including "superficial wounds" or broadly disclose treatment of "sexual dysfunction" or the use of a "nitric oxide precursor means" as is explicitly recited by at least claim 64; nor does the specification as filed broadly disclose the use of "alkyls of L-arginine" as recited by at least

claim 67 nor does the specification as filed broadly disclose a method of increasing "growth and repair of cells" as in claim 71 or the agents for producing a hostile biophysical environment recited in claims 73, 77, 79 and 81 with the exception of sodium chloride.

Claims 33-35, 38-41,70-73,75-77, 79 and 81 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is intended by the agents in claims 73, 77, 79 and 81 which are not substances.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

Claims 64-66 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saavedra et al. (USP 5,632,981).

Saavedra et al. disclose a process for treating impotence in which a nitric oxide releasing material is incorporated into a condom (column 10 lines 20-35). The composition may be in the form of liposomes in a gel or patch at column 9 lines 51-65 and applied topically (column 11 lines 16-26) and may be non-aqueous (note the paragraph bridging columns 11 and 12). Since the nitric oxide increases blood flow to issue, increased blood flow would reasonably appear to be inherent. Phosphate buffer (a salt containing material) may be added at column 12 lines 48-56, or "saline" may be added at column 11 lines 40-52.

Product-by-process claims are not rejected using the approach set out in Graham v. Deere. It is applicant's burden to show that there is a non-obvious difference between the product of a product-by-process claim and a prior art product which reasonably appears to be the same or only slightly different whether or not the prior art product is produced in the same manner as the claimed product. Note In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972) and In re Thorpe, 227 USPQ 964 (CAFC 1985) in this regard.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-35, 38-41, 51-53, 56-59 and 61-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,207,713. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of increasing blood flow is embraced by the method of increasing blood flow of the patent claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Mullis whose telephone number is (703) 308-2820. The examiner can normally be reached on Monday-Friday from 9:30 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck, can be

reached on (703) 308-2462. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-2351.

J. Mullis:cdc

September 24, 2003

Jeffrey Mullis
Primary Examiner
Art Unit 1711